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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/723,248

11/25/2003

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

PAPER NUMBER

3733

NOTIFICATION DATE

DELIVERY MODE

10/18/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/723,248

Applicant(s)

ARRAMON, YVES P.

Examiner

Jerry Cumberledge

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 08/06/2007.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The affidavit filed on 08/06/2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the Mazzuca reference.

Initially, the affidavit does not state that the invention was conceived and reduced to practice in the United States, a NAFTA country or a WTO member country. (MPEP 715)(37 CFR 1.131).

Secondly, the evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Mazzuca reference. Applicant has stated that the device was reduced to practice prior to the effective date of the Mazzuca reference, however a general allegation that the invention was completed prior to the date of the reference is not sufficient. *Ex parte Saunders*, 1883 C.D. 23, 23 O.G. 1224 (Comm'r Pat. 1883)(MPEP 715.07). There is no evidence supporting that the invention was successfully reduced to practice prior to the effective date of Mazzuca (e.g. test records, management reports, photographs of the prototype device).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25, 26, 32 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Mazzuca et al. (US Pub. 2005/0070915 A1).

Mazzuca et al. disclose an implant material injection system adapted for performing a percutaneous vertebroplasty procedure comprising: a remote actuator (Fig. 2, ref. 40); a pump (Fig. 2, ref. 100) comprising a piston (Fig. 2, ref. 66) and a drive chamber (Fig. 2, ref. 60), the pump having a distal end (Fig. 2, end near ref. 64) adapted to connect with a cannula (Fig. 2, ref. 30), the drive chamber adapted to hold implant material (paragraph 0054, lines 1-3) (paragraph 0056, lines 10-12), the piston adapted to drive the implant material through the distal end of the drive chamber to an implant site (paragraph 0057); a control line (Fig. 4, ref. 15) connecting the remote actuator and the pump (Fig. 4), the control line adapted to advance the piston (paragraph 0053, lines 7-9); and wherein the implant material comprises a flowable hard tissue implant material (paragraph 0054). The control line comprises a fluid column adapted to advance the piston (column 0053). The system further comprises a cannula (Fig. 2, ref. 30) removably connected with the distal end of the drive chamber. The implant material comprises polymethylmethacrylate (paragraph 0054).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzuca et al. (US Pub. 2005/0070915 A1).

With regard to claims 27, 28 and 30, Mazzuca et al. disclose the claimed invention except for the control line has a length of about one foot; the control line has a length of about 36 inches; the control line has a length of about 48 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the control line of Mazzuca et al. at a length of about one foot/ of about 36 inches/ of about 48 inches, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With regard to claims 29 and 31, Mazzuca et al. disclose the claimed invention except for the control line having a length of at least 36 inches; the control line having a length greater than 48 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the control line having a length of at least 36 inches/ the control line having a length greater than 48 inches, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzuca et al. (US Pub. 2005/0070915 A1) in view of Bischof et al. (US Pat. 4,915,688) further in view of Lautenschlager et al. (US Pat. 5,902,839).

Mazzuca et al. disclose the claimed invention except for the system further comprising an implant material reservoir connected with the pump, the pump adapted to draw implant material from the material reservoir into the drive chamber.

Bischof et al. disclose a device comprising implant material reservoirs (Fig. 1, refs. 20 and 21) connected to a pump (column 3, lines 58-64), the pump being adapted to draw implant material from the material reservoir into the drive chamber (column 3, lines 58-64), the reservoirs being useful for holding supplies of different components and keeping them separate from the other components of a predetermined mixture (column 2, lines 54-57) until the time that they are required to be mixed and administered to a patient (column 2, lines 24-31).

Lautenschlager et al. disclose a bone cement (*i.e.* an implant material) that comprises at least two liquid components (column 2, lines 21-24), which can be held in separate containers in a single cement delivery device (column 3, lines 15-17) and mixed just prior to being delivered to the patient (column 2, lines 21, 24), the two separate liquid components being used in a delivery device having two separate storage components, in order to keep the components separate until they are required to be mixed (column 3, lines 15-19) after which they will harden (column 7, lines 24-26). An advantage of this system is that it introduces less air into the bone cement as it is being mixed (column 3, lines 15-23).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Mazzuca et al., which is used to deliver implant material (Mazzuca et al., paragraph 0054), with the implant material reservoirs of Bischof et al., in order to hold a bone cement (i.e. implant material) of Lautenschlager et al. The implant material reservoirs of Bischof et al. would provide the device of Mazzuca et al. with at least two separate containers to hold the separate components of the bone cement of Lautenschlager et al. This set-up would be advantageous because it would allow for less air to be introduced into the bone cement while it is being mixed (Lautenschlager, column 3, lines 15-23).

With regard to statements of intended use and other functional statements (e.g. "...are adapted to draw implant material..." and "...adapted to drive said piston..." and movement corresponds to 1 to 1 with movement..."), they do not impose any structural limitations on the claims distinguishable over the device of Bischof et al. in view of Kline, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC




EDUARDO ROBERT
SUPERVISORY PATENT EXAMINER